REMARKS

The Office action dated August 3, 2010 is acknowledged. Claims 1-90 are pending in the instant application. According to the Office action, claims 1-6, 11-23, 42-46 and 83-90 are rejected and claims 7-10, 24-41 and 47-82 have been withdrawn.

By the present response, claims 1, 6 and 42 have been amended and claims 13 and 14 have been canceled. Claim 7, which is withdrawn, is also amended for informal purposes only. Support for the amendment to claim 1 can be found throughout the present specification, such as at paragraphs [0029], [0049] and [0050]. Support for the amendment to claim 6 can be found throughout the present specification, such as at paragraphs [0029] and [0049]. Reconsideration is respectfully requested in light of the amendments being made hereby and the arguments made herein. No new matter has been added.

Rejection of Claims 1-6, 11-23, 42-46 and 83-90 under 35 U.S.C. 103(a)

Claims 1-6, 11-23, 42-46 and 83-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2001/0006677 (McGinity, et al.) in view of U.S. Patent No. 6,177,096 (Zerbe, et al.) (although it appears the rejection may have been withdrawn in regard to claims 6, 11-19, 42-46 and 87-90 and thus pertaining to claims 1-5, 20-23 and 83-86).

As previously argued by the Examiner, McGinity, et al. teach effervescent polymeric film drug delivery systems that are adapted for direct oral or buccal administration and that the formulations provide for a rapid rate of release of an active ingredient that ranges from immediate to a period of about 10 minutes. The Examiner

also previously argued that the reference teaches every limitation of the presently claimed invention, except for the limitation that the coating compound composition is dried.

The Examiner in turn referred to Zerbe, et al. for teaching water soluble film for oral administration with instant wettability, and for teaching the missing limitations of McGinity, et al. except for the limitation of at least one or two gas forming agents. However, in this regard, the Examiner stated that when using a non-aqueous solvent in the process for making the compositions of McGinity, et al., it would have been obvious to have dried the film to remove the solvent with the motivation to form a dry film, as disclosed by Zerbe, et al. The Examiner also concluded that it would have been obvious to use a non aqueous solvent to dissolve the components of the film composition, cast the films and dry them to make the compositions of McGinity, et al. motivated by the desire to avoid high temperatures that may degrade the effervescent components by using a method disclosed in the art that is used to make water dispersible films with a compatible solvent.

Regarding claims 84 and 88, the Examiner has stated that it is generally *prima facie* obvious to select a known material for incorporation into a composition based on its recognized suitability for its intended use. Therefore, the Examiner concluded that it would have been obvious to one of ordinary skill in the art to have used an acrylate polymer in the composition of McGinity, et al. motivated by the desire to use a water-dispersible polyacrylate for its function as a binding agent in a water dispersible film.

In the present Final Office action, the Examiner argues that according to *KSR v. Teleflex* "obviousness to try" is permissible and that there is a market pressure in the

medical/pharmaceutical industries to make films using a method that does not degrade the extruded materials. Thus, the Examiner concludes that it would have been obvious to one of ordinary skill in the art to look to other methods in order to avoid this, i.e., to use the methods of Zerbe, et al. to make the films of McGinity, et al. especially when non-aqueous solvents are used.

Claims 6, 11-19, 42-46 and 87-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGinity, et al. in view of U.S. Patent No. 5,639,475 (Bettman, et al.). The Examiner argues in the present Final Office action that McGinity, et al. teach the limitations of the referenced claims, but fails to disclose that the gas forming components are present in microencapsulated form.

The Examiner refers to Bettman, et al. for disclosing effervescent microcapsules which comprise an effervescent mixture of citric acid and sodium bicarbonate – the effervescent microcapsules being useful in formulating taste-masked effervescent chewable tablets also containing microencapsulated, unpleasant tasting drugs such as non-steroidal, anti-inflammatory, NSAID drugs. The Examiner also states that the taste-masked effervescent microcapsules maintain a controlled effervescent reaction in the mouth without a "burst" effect and that the effervescent microcapsules provide increased product stability and less need for humidity control during processing, for example, manufacture on a conventional tablet press.

The Examiner does state that the reference differs from the present claims insofar as it does not disclose the preparation is a film. However, the Examiner concludes that it would have been obvious to one of ordinary skill in the art to have microencapsulated the

effervescent mixture of McGinity, et al. motivated by the desire to mask the unpleasant taste, maintain a controlled effervescent reaction in the mouth without a "burst" effect and provide increased product stability and less need for humidity control during processing of the mixture as disclosed by Bettman, et al.

The Applicants respectfully submit that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all of the claim limitation. It is also well-established that the prior art cannot teach away from the claimed invention. The Applicants respectfully submit that one skilled in the art would have no suggestion or motivation to combine the aforementioned references in order to arrive at the present invention. Additionally, even if one skilled in the art were to consider McGinity, et al. fail alone, or in combination with the cited secondary reference, each and every limitation of the present invention would not be disclosed, nor would there be a reasonable expectation of success if the aforementioned references were to be considered as the prior art teaches away. In regards to *KSR v. Teleflex*, a reasonable expectation of success is still required. See Examination Guidelines Update: Developments in the Obviousness Inquiry After *KSR v. Teleflex*, Federal Register / Vol. 75, No. 169, September 1, 2010 / Notices, which states: "However, familiar lines of argument still apply, including teaching away from the claimed invention, lack of a reasonable explanation of success and unexpected results." As discussed below, one skilled in the art would not have had a reasonable

expectation of success of arriving at the presently claimed invention based on the teachings of McGinity, et al. in view of Bettman, et al.

The Applicants respectfully disagree with the Examiner's conclusion set forth in the Office action. Claim 1 as amended herewith recites a process for producing a preparation whereby said preparation is present in the form of a film that disintegrates in water or in aqueous medium within one second to one minute if present in the oral cavity, whereby said preparation contains at least one gas-forming component that is present in micro-encapsulated form comprising the steps of preparing a coating which contains the compounds of the preparation including said at least one gas-forming component by dissolving or suspending in an aqueous medium.

Accordingly, the presently claimed invention is directed to a process for the preparation of a rapidly disintegrating film that contains gas-forming components. As these gas-forming components are present in micro-encapsulated form, the presently claimed inventive process for producing the preparation can be carried out in an aqueous medium without reaction of the gas-forming components. Only under the conditions present in the oral cavity, such as a particular pH value or body temperature, will the gas-forming reaction be activated (see, for example, paragraphs [0049] and [0050] of the specification as published).

McGinity, et al. teach a composition comprising both hot-melt extrudable water soluble or swellable effervescent film binders and effervescent couple that are placed into a mixer and mixed until blended to form an effervescent mixture that is subsequently hot-melt extruded (paragraph [0094]). The process according to McGinity, et al. does not

allow the presence of water at all. If an effervescent couple as described in the McGinity, et al. reference was exposed to water during hot-melt extrusion, said effervescent couple would react by forming a gas prematurely under the conditions that are present during hot-melt extrusion, such as increased temperature. Accordingly, the presently claimed inventive process differs in many aspects from the disclosure of McGinity, et al. In particular, McGinity, et al. do not disclose gas-forming components that are present in micro-encapsulated form so that a rapidly disintegratable film can also be prepared in the presence of an aqueous medium.

Zerbe, et al. fail to make up for any of the numerous deficiencies of McGinity, et al. Accordingly, a combination of teachings of McGinity, et al. with Zerbe, et al. would still fail to teach each and every limitation of the presently claimed invention, nor would there be any reasonable expectation of successfully arriving at the presently claimed invention.

Turning now to the second obviousness rejection, the Applicants also respectfully disagree with the Examiner due to the numerous deficiencies of McGinity, et al. The subject matter of present claim 6 is directed to the preparation in the form of a film or wafer that rapidly disintegrates in water or in aqueous medium within one second to one minute and contains at least one gas-forming component that produces a gas when present in the oral cavity, whereby the gas-forming components are present in micro-encapsulated form. Thus, the presently claimed invention of claim 6 differs from the disclosure of McGinity, et al. in at least the fact that it disintegrates in an aqueous medium very rapidly and contains gas-forming components in micro-encapsulated form as discussed above.

McGinity, et al. merely describe that the effervescent film disclosed therein releases all or a defined portion of the active ingredient within about 10 minutes after placement of the film in contact with an aqueous solution or a surface having moisture (paragraph [0037]). However, the McGinity, et al. reference is completely silent about the fact that the whole film already disintegrates within one second to one minute. Moreover, McGinity, et al. fail to teach or disclose that the gas-forming components are present in micro-encapsulated form.

Bettman, et al. fail to make up for the numerous deficiencies of McGinity, et al. First, Bettman, et al. is entirely silent about how to obtain films that rapidly disintegrate in an aqueous medium. Secondly, although Bettman, et al. disclose some sort of microcapsules that comprise effervescent mixtures, the type of micro-encapsulation according to Bettman, et al. is totally different from the type of micro-encapsulation as recited in the presently claimed invention. In particular, Bettman, et al. disclose effervescent microcapsules that are present in chewable tablets. These effervescent microcapsules maintain a controlled effervescent reaction in the mouth without a burst effect (col. 2, lines 11-22). Consequently, the effervescent microcapsules according to Bettman, et al. only release the gas-forming components when being chewed. In contrast to Bettman, et al., the micro-encapsulation of the presently claimed invention is selected so that the gas-forming reaction is already activated in the oral cavity (paragraph [0049]) and thus the wafer is virtually "blown-up" by the gas bubbles formed in its interior (paragraph [0012]). Accordingly, Bettman, et al. disclose micro-encapsulated effervescent capsules that are quite different from the presently claimed gas-forming

components in micro-encapsulated form.

It is further submitted that Bettman, et al. only disclose effervescent microcapsules that are present in chewable tablets (col. 1, lines 4-6). The effervescent microcapsules are used in order to mask an unpleasant tasting pharmaceutical material that is present in the chewable tablets. As the tablets are chewed upon for a long period, the gas-forming components according to Bettman, et al. are micro-encapsulated with a type of micro-encapsulation that avoids release of the gas-forming components immediately after intake. In contrast to the disclosure of Bettman, et al., the gas-forming reactions of the presently claimed invention are rapidly activated and thus the wafer essentially "blows up" immediately after intake leading to an accelerated release of active substance (paragraph [0012]).

As Bettman, et al. only teach and describe micro-encapsulated effervescent couples that are useful in combination with chewable tablets, it is submitted that the Bettman, et al. reference pertains to a totally different area of art as that of the presently claimed invention. In turn, it is submitted that one skilled in the art would not consider Bettman, et al. when faced with the task of providing films that disintegrate rapidly (i.e., within one second to one minute) and allow for accelerated release of active substances.

Thus, Bettman, et al. fail to make up for any of the numerous deficiencies of McGinity, et al. Accordingly, a combination of teachings of McGinity, et al. with Bettman, et al. would still fail to teach each and every limitation of the presently claimed invention, nor would there be any reasonable expectation of successfully arriving at the presently claimed invention.

It is therefore respectfully submitted that the present invention defined in the present claims is patentably distinguishable over the combination of prior art teachings under 35 U.S.C. 103(a). Based on the aforementioned differences, each and every element of the present invention recited in the present claims is not set forth in the McGinity, et al., alone or in combination with the cited secondary references. In addition, Zerbe, et al. and Bettman, et al. fail to make up for any of the missing limitations of McGinity, et al. Moreover, one skilled in the art would not be motivated to combine said references or to modify McGinity, et al. to arrive at the presently claimed invention. Therefore, the Applicants respectfully request that this rejection be withdrawn.

Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicant strongly urges that the obviousness-type rejection and anticipation rejection be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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